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110TH CONGRESS
2D SESSION

H. R. 7077

To amend title XIX of the Social Security System to provide additional funds for the qualifying individual (QI) program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2008

Mr. DINGELL introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XIX of the Social Security System to provide additional funds for the qualifying individual (QI) program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "QI Program Supplemental Funding Act of 2008".

SEC. 2. FUNDING FOR THE QUALIFYING INDIVIDUAL (QI) PROGRAM.

Section 1933(g)(2) of the Social Security Act (42 U.S.C. 1396u–3(g)(2)), as amended by section 111(b) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is amended—

(1) in subparagraph (I), by striking "$300,000,000" and inserting "$315,000,000"; and

(2) in subparagraph (J), by striking "$100,000,000" and inserting "$130,000,000".

SEC. 3. MANDATORY USE OF STATE PUBLIC ASSISTANCE REPORTING INFORMATION SYSTEM (PARIS) PROJECT.

(a) IN GENERAL.—Section 1903(r) of the Social Security Act (42 U.S.C. 1396b(r)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by inserting ", in addition to meeting the requirements of paragraph (3)," after "a State must"; and

(2) by adding at the end the following new paragraph:

"(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any suc-

cessor system), including matching with medical assistance programs operated by other States.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) take effect on October 1, 2009.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

SEC. 4. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

"(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

"(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

"(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

"(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this sub-

section in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

"(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

"(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

"(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

"(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

"(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

"(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

"(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

"(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

"(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which

was approved by the Secretary under such section.

"(3) LIMITATIONS.—

"(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

"(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

"(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any

drug with respect to which an election is made under paragraph (2)(A).".

(b) TRANSITIONAL RULES.—

(1) With respect to a patent issued on or before the date of the enactment of this Act, any patent information required to be filed with the Secretary of Health and Human Services under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (v)(1) of such section 505 (as added by this section) applies shall be filed with the Secretary not later than 60 days after the date of the enactment of this Act.

(2) With respect to any patent information referred to in paragraph (1) of this subsection that is filed with the Secretary within the 60-day period after the date of the enactment of this Act, the Secretary shall publish such information in the electronic version of the list referred to at section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) as soon as it is received, but in no event later than the date that is 90 days after the enactment of this Act.

(3) With respect to any patent information referred to in paragraph (1) that is filed with the Sec-

retary within the 60-day period after the date of enactment of this Act, each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the date of the enactment of this Act, a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain a certification described in paragraph (2)(A)(vii)(IV) of such section 505(j) with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)).

SEC. 5. CLARIFICATION OF AUTHORITY FOR USE OF MEDICAID INTEGRITY PROGRAM FUNDS.

(a) CLARIFICATION OF AUTHORITY FOR USE OF FUNDS.—

(1) IN GENERAL.—Section 1936 of the Social Security Act (42 U.S.C. 1396u–6) is amended—

(A) in subsection (b)(4), by striking "Education of" and inserting "Education or training, including at such national, State, or regional conferences as the Secretary may establish, of State or local officers, employees, or independent contractors responsible for the adminis-

tration or the supervision of the administration of the State plan under this title,"; and

(B) in subsection (e), by striking paragraph (2) and inserting the following:

"(2) AVAILABILITY; AUTHORITY FOR USE OF FUNDS.—

"(A) AVAILABILITY.—Amounts appropriated pursuant to paragraph (1) shall remain available until expended.

"(B) AUTHORITY FOR USE OF FUNDS FOR TRANSPORTATION AND TRAVEL EXPENSES FOR ATTENDEES AT EDUCATION, TRAINING, OR CONSULTATIVE ACTIVITIES.—

"(i) IN GENERAL.—The Secretary may use amounts appropriated pursuant to paragraph (1) to pay for transportation and the travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business, of individuals described in subsection (b)(4) who attend education, training, or consultative activi-

ties conducted under the authority of that subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect as if included in the enactment of section 1936 of the Social Security Act, as added by section 6034(a) of the Deficit Reduction Act of 2005 (Public Law 109–171).

(b) PUBLIC DISCLOSURE.—

(1) IN GENERAL.—Section 1936(e)(2)(B) of such Act (42 U.S.C. 1396u–6(e)(2)(B)), as added by subsection (a) of this section, is amended by adding at the end the following:

"(ii) PUBLIC DISCLOSURE.—The Secretary shall make available on a website of the Centers for Medicare & Medicaid Services that is accessible to the public—

"(I) the total amount of funds expended for each conference conducted under the authority of subsection (b)(4); and

"(II) the amount of funds expended for each such conference that were for transportation and for travel expenses.".

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(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to conferences conducted under the authority of section 1936(b)(4) of the Social Security Act (42 U.S.C. 1396u–6(b)(4)) after the date of enactment of this Act.

SEC. 6. FUNDING FOR THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking "$2,220,000,000" and inserting "$2,290,000,000".

SEC. 7. TECHNICAL CORRECTION.

Section 1941(b)(1)(B) of the Social Security Act, as added by section 7002(b) of the Supplemental Appropriations Act, 2008, is amended by inserting "each of" after "for".

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